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EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Brian Poor on December 16, 2008.

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The application has been amended as follows: Claim 1 has been amended as follows: --

1. (Currently amended) A tangential flow filtration device for preparing a cell population enriched for leukocytes, comprising:

a remover unit having a cross-flow chamber, a filtrate chamber and a filter disposed therebetween -- **the filter having a retentate surface and a filtrate surface** --, the filter in fluid communication with the cross-flow chamber and the filtrate chamber;

the cross-flow chamber having an inlet and an outlet, the inlet disposed to introduce the cell population comprising a sample of blood constituents comprising leukocytes into the cross-flow chamber and parallel to the -- **retentate** -- surface of the filter; and the outlet centrally disposed in a portion of the cross-flow chamber opposite the filter -- **retentate** -- surface;

the filter having an average pore size ranging from about 1 to about 10 microns; such that flow of the sample of blood constituents across the filter enriches the cell population comprising the sample of blood constituents for leukocytes. -- .

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Claim 25 has been amended as follows: --

25. (Currently amended) A method for separating leukocytes from a cell population comprising a sample of blood constituents from a subject wherein the sample comprises leukocytes, the method comprising:

(1) introducing the sample into a remover unit -- **wherein the remover unit comprises a cross-flow chamber, a filtrate chamber and a filter disposed therebetween, the filter having a retentate surface and a filter surface, the filter in fluid communication with the cross-flow chamber and the filtrate chamber; the cross-flow chamber having an inlet and an outlet, the inlet disposed to introduce the cell population comprising the sample of blood constituents comprising the leukocytes from a source into the cross-flow chamber and parallel to the retentate surface of the filter, and the outlet centrally disposed in a portion of the cross-flow chamber opposite the filter retentate** -- surface through an inlet in the ~~remover unit~~;

(2) subjecting the sample to cross-flow substantially parallel to a filter having a pore size of about 1 to about 10 microns;

(3) subjecting the fluid to filtration through the filter; and

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(4) selectively removing non-leukocyte blood constituents from the sample
-- **through the filter and removing the leukocytes through the centrally disposed outlet** -- to form a cell population enriched for leukocytes.

-- .

Claims 35-39,50-59 and 61-69 have been canceled, in view of potential enablement issues.

Claim 40 has been amended as follows: --

40. (Currently amended) A method for enriching a cell population comprising a sample of blood constituents for leukocytes, comprising:

(1) introducing the cell population comprising the sample into a tangential flow filtration (TFF) unit, the TFF unit comprising a cross-flow chamber, a filtrate chamber, and a filter in fluid communication with the cross-flow chamber and the filtrate chamber -- **, the filter having a retentate surface and a filter surface, the cross-flow chamber having an inlet and an outlet, the inlet disposed to introduce the cell population comprising the sample of blood constituents comprising leukocytes from a source into the cross-flow chamber and parallel to the retentate surface of the filter, and the outlet disposed in a portion of the cross-flow chamber opposite the filter retentate surface;** the filter having a pore size of about 1 to about 10 microns;

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(2) recirculating the sample through the TFF unit at a predetermined input rate and a predetermined filtration rate, the predetermined input rate at least five times the predetermined filtration rate; wherein the predetermined filtration rate is less than the unopposed filtration rate for the filter; and

(3) isolating a cell population enriched for leukocytes **through the outlet centrally disposed in the portion of the cross-flow chamber opposite the filter retentate surface.** -- .

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The following is an examiner's statement of reasons for allowance: Each of independent claims 1, 25 and 40 , and claims dependent therefrom are now distinguished over the applied prior art of record as well as newly cited Rossini et al patent 5,026,365 in view of recitation of the outlet centrally disposed in the cross-flow chamber opposite the retentate surface of the filter, and operative to collect the cell population enriched for leukocytes (for claims 25 and 40). Cross-flow filter chambers operative to separate leukocytes or other blood constituents from blood samples only recite a retentate outlet, as is true for instance in Brody et al of record and newly recited Rossini et al patent 5,026,365 and Prince et al patent 6,491,819. Brody et al does disclose a filtrate outlet centrally disposed in a filtrate chamber for dispensing blood constituents passing through the filter, however not suggesting the claimed centrally disposed retentate outlet. Support for the Examiners amendment is found at page 5, line 19-page 6, line 15 and page 16, lines 23-28 of the Instant Specification.

Claims 23 and 24 are similarly distinguished in view of recitations of the inlet being disposed above the filter to introduce the fluid into the cross-flow chamber together with the outlet being centrally disposed in the upper portion of the cross-flow chamber.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

JWD

12/17/2008

/Joseph W. Drodge/

Primary Examiner, Art Unit 1797